



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

Address: COMMISSIONER FOR PATENTS

P.O. Box 1450

Alexandria, Virginia 22313-1450

www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/537,704	12/12/2005	Richard James Lewis	16095	6539
23389 7590 03/18/2010 SCULLY SCOTT MURPHY & PRESSER, PC 400 GARDEN CITY PLAZA SUITE 300 GARDEN CITY, NY 11530				
EXAMINER				
AUDET, MAURY A				
ART UNIT		PAPER NUMBER		
1654				
MAIL DATE		DELIVERY MODE		
03/18/2010		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/537,704

Applicant(s)

LEWIS ET AL.

Examiner

MAURY AUDET

Art Unit

1654

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 1/29/10.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7, 15-19 and 22 is/are pending in the application.
- 4a) Of the above claim(s) 17-19 and 22 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 15-16 is/are allowed.
- 6) ☒ Claim(s) 1-3, 6 and 7 is/are rejected.
- 7) ☒ Claim(s) 4 and 5 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

As stated previously, The present Application has been transferred from former Examiner Young to the present Examiner.

Applicant's filing of the RCE and Terminal Disclaimer on 1/29/10 are acknowledged.

However, the Terminal Disclaimer over US 7,507,717 (SN 10/537,088) has been disapproved. As stated by the Paralegal on 3/15/10:

37 CFR 1.321 (c)(3) requires that a TD "Include a provision that any patent granted on that application or any patent subject to the reexamination proceeding shall be enforceable only for and during such period that said patent is commonly owned with the application or patent which formed the basis for the judicially created double patenting." [Emphasis added]

The words "legal title" do not include common ownership as to equitable title.

Thus, the Double Patenting rejection is maintained (though actual Rejection rather than provisional with the issuance of '088) and the position in the Advisory Action is maintained, repeated below for continuity of record:

I. First Ground: Applicant has changed the scope of the claims by amending Claim 4 to include to new species SEQ ID NO: 7 and 8, which were not pending at the time of the Final Rejection, or searched/examined as to being free of the art (even if the genus was, as Applicant has indicated; these nevertheless have to be individually searched/examined and determined allowable). Applicant asserts that SEQ ID NO: 7-8 were inadvertently deleted from the claims. Even if inadvertent, this changed the scope of the claims and the search/examination thereof. Which is clear on the record in the Final Rejection, where the Examiner accommodated Applicant's request for rejoinder of certain SEQ ID NOS.; none of which were SEQ ID NOS: 7-8:

"Restriction Election and Traversal Acknowledged:

The FINAL restriction requirement is maintained as provided previously, as to the methods, BUT, the peptides have been rejoined. Specifically, Applicant's request for the rejoinder of the remaining, amended five (5) SEQ ID NOS: 5-6, 9, and 10-11, as well as the amended genus peptide formula of claim 1 is EXTENDED.

Art Unit: 1654

Claim 5, product, is hereby rejoined.

The method claims will be rejoined under In re Ochiai upon the Allowability of the product claims to which they depend.

Thereafter, upon allowability of any method claims formerly within a different group, the FINALITY of the restriction requirement as to these will be VACATED."

II. Second Grounds: SEQ ID NOS: 7-8 are amended into claim 4, which still has an outstanding Objection as depending from Obviousness Double Patenting Rejected base Claim 1 over SN '088's overlapping SEQ ID NO: 5; which Applicant acknowledges is now issued Patent US 7507717 B2. Thus making the Double Patenting Rejection no longer merely Provisional, since that application has Issued.

As Applicant indicated in his Summary of the Interview filed 11/19/09, 20 days after the After Final Amendment:

"The undersigned attorney also indicated to the Examiner that Applicants intended to file a terminal disclaimer to address the obviousness type double patenting rejection."

For reasons the Examiner is uncertain, Applicant has not filed this Terminal Disclaimer. Like the first ground above, SEQ ID NOS: 7-8 have not been searched/examined to determine if there are claimed species or obvious genus, that overlap in the now '717 B2 Patent, with SEQ ID NOS: 7-8.

Thus, the Double Patenting Rejection, the only rejection of record, remains outstanding (no longer just a provisional, per Applicant's notice the application has Issued).

[The 35 USC 112 2nd Rejection also remains outstanding since the Claim Amendments cannot be entered for the reasons stated. But it is noted the amendments made would overcome the 112 2 rejection, at such time as these amendments become part of the record.].

III. Should Applicant not accept the allowance of claims 15-16 - per claimset filed 12/19/08, still of record - noted above (Allowed in Final Rejection), Applicant may wish to consider the filing of RCE in order to have all the amended claims considered, including those drawn to SEQ ID NOS: 7-8, and to file the Terminal Disclaimer.

IV. It is noted that the (Withdrawn) claims, drawn to Methods of Use, may be subject to 35 USC 112 1st Enablement issues, should Applicant seek rejoinder thereof under In re Ochiai, once the claims are amended to an Allowable Product.

Restriction election and traversal acknowledged

The FINAL restriction requirement is maintained as provided previously, as to the methods, BUT, the peptides have been rejoined. Specifically, Applicant's request for the rejoinder of the remaining, amended five (5) SEQ ID NOS: 5-6, 9, and 10-11, as well as the amended genus peptide formula of claim 1 is EXTENDED.

Claim 5, product, is hereby rejoined.

The method claims will be rejoined under In re Ochiai upon the Allowability of the product claims to which they depend.

Thereafter, upon allowability of any method claims formerly within a different group, the FINALITY of the restriction requirement as to these will be VACATED.

Claims 15-16 are directed to an allowable product. Based on Applicant's request of the Examiner to rejoin the product of claim 5, which the Examiner has extended, claim 5 has been rejoined and previously withdrawn from consideration as a result of a restriction requirement, and are hereby rejoined and fully examined for patentability under 37 CFR 1.104.

Because all claims previously withdrawn from consideration under 37 CFR 1.142 have been rejoined, **the restriction requirement, in part, 10/30/06, as set forth in the Office action mailed on 10/30/06 is hereby withdrawn.** In view of the withdrawal of the restriction requirement as to the rejoined inventions, applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim

that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Once the restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The original restriction requirement, as noted previously, was that Applicant's election with traverse of Group I, claims 1-7, and the species election of SEQ ID NO: 4, in the reply filed on December 4, 2006 is acknowledged. The traversal is on the ground(s) that the claims have unity of invention under PCT Rule 13.1. This is not found persuasive because it is proper to rely on evaluation of novelty or unobviousness when making a determination of unity of invention, the unity of invention of the instant application's claim set being broken by the prior art cited by the Examiner, Balaji et al. (*J. Biol. Chem.* 275(50):39516-22, 2000) does teach the special technical feature of the instant claims, the structure of the chi-conotoxins. In regards the linking claim 8 recited in Applicant's response on page 4, it is drawn to non-elected inventions II-VII. Claim 5 is withdrawn as being drawn to non-elected species, the elected species being found unpatentable (see below).

Double Patenting Rejection

The rejection is maintained for the reasons of record –but now under actual Double Patenting rejection, as opposed to provisional, with the allowance of the '088 application; which

Art Unit: 1654

has the same priority date as the present application, and remains under examination on the merits as to one or more overlapping peptides (e.g. SEQ ID NO: 5).

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-3 as rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 2, 5, 6, 12, 13, 15-21, 38-41, 43, 45, 47, and 49 of US copending Application No. 10/537,088, is maintained for the reasons of record as indicated above.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the species of conotoxin peptide claimed in the instant 10/537,704 as the elected peptide species SEQ ID NO: 4 is part of the Markush group comprising the conotoxin peptides claimed in the copending 10/537,088 as SEQ ID NO: 4 (in copending claim 2) and SEQ ID NO: 5 (in copending claims 5 and 6). Claims depending from the copending claims 2, 5 and 6 are directed towards further narrowing the Markush group, rendering the instant SEQ ID NO: 4

of 10/537,704 as a species of an ever smaller genus. The peptide sequence SEQ ID NO: 3 (instant claims 1 and 2), which is the foundation of the instant claim set in 10/537,704 is similarly within the bounds of the SEQ ID NO: 4 of the copending 10/537,088.

Claim Objections

Claims 4-5 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Request for Information: In re Ochiai Rejoinder of Methods of Use Claims

As stated previously, in anticipation of the future rejoinder of the myriad methods of use of these compounds, Applicant is asked to supply the Office with specification support (e.g. tests, etc.) or literature support that the native peptide of these modified peptides bearing a substantial core structure herein are known or have been shown to treat all these myriad of methods.

Conclusion

Claims 15-16 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MAURY AUDET whose telephone number is (571)272-0960. The examiner can normally be reached on M-Th. 7AM-5:30PM (10 Hrs.).

Art Unit: 1654

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MA, 4/13/09

/Maury Audet/
Primary Examiner, Art Unit 1654